Exhibit B

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION **THIS DOCUMENT RELATES TO WAVE 2**	**Master File No. 2:12-MD-02327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

RULE 26 EXPERT REPORT OF JOHN MIKLOS, M.D.
TVT-SECUR

The following report is provided pursuant to Rule 26 of the Federal Rules of Civil Procedure.

I. QUALIFICATIONS

I received my BS in Biology from Juniata College in Huntingdon, Pennsylvania in 1982 and graduated with a MS in Physiology and a MD degree from the Medical University of South Carolina School of Medicine, in Charleston, South Carolina in 1985 and 1989, respectively. I did my residency training in Obstetrics and Gynecology at Hahnemann University Hospital in Philadelphia, Pennsylvania between 1989-1993. Then I completed my first two-year fellowship at Good Samaritan Hospital in Cincinnati, Ohio in Urogynecology & Reconstructive Pelvic Surgery in 1995. I went on to complete a second fellowship in minimally invasive reconstructive pelvic surgery at Atlanta Laparoscopic Training Center in Atlanta, Georgia in 1997. I was appointed and served as the Director of Urogyencology and Reconstructive Pelvic Surgery at Georgia Baptist Medical Center (1995-1997). I was a clinical instructor at the Advanced Laparoscopy Training Center, Marietta, Georgia (1995-1999) and at the Medical

College of Georgia in Augusta (1996-1999). I became the Director of Urogynecology for the Atlanta Urogynecology Associates (1997-2014) as well as the International Urogynecology Associates offices in Beverly Hills, CA and Atlanta, Georgia (2012-2014). I have recently been awarded the title of full adjuvant Professor in Obstetrics & Gynecology specializing in Urogynecology at Emory University in Atlanta, Georgia. I have been in a practice exclusively dedicated to female pelvic floor disease and its surgical correction for 18 years. My partner, Robert D. Moore, D.O., and I often operate together as a team. During this time, my partner and I have operated on approximately 8,000 patients from 50 states and 52 countries.

I received and maintain my Board Certifications in Obstetrics and Gynecology and Female Pelvic Medicine and Reconstructive Surgery. I am a Fellow in good standing of: American College of Obstetrics and Gynecology (FACOG), American College of Surgeons (FACS), and a member of: American Association of Gynecologic Laparoscopy (AAGL), American Urogynecology Society (AUGS), American Urologic Association (AUA) and Society of Gynecologic Surgeons (SGS).

I have been a member of the American Urogynecology Society since 1993 and have served on the Board of Directors and taught postgraduate courses at the combined International Urogynecology Association (IUGA) and American Urogynecology Society (AUGS) Meetings including: Laparoscopic vaginal reconstructive vaginal surgery and the surgical treatment of mesh complications after vaginal mesh reconstructive surgery. I have also been a member of the American Association of Gynecologic Laparoscopic Surgeons (AAGL) since 1992 and have served on the AAGL Board of Advisors (2008-2010) and the Urogynecology Special Interest Group (2010-2014). In 2014 I was nominated as one of two candidates for a position as an AAGL trustee.

I was nominated for Association of Professors of Gynecology and Obstetrics (APGO) "Excellence in Training" Award in 1992 and received the APGO Award in 1997. I have been given various surgical and scientific awards including: AAGL - Jerome Hoffman Prize Paper Award (2000), AAGL - Kurt Semm Award for Excellence in Pelviscopy (2007), AAGL - Annual Golden Laparoscope Award (2000 and 2014).

I have been a journal reviewer for Obstetrics and Gynecology, International Urogynecology Journal and Pelvic Floor Dysfunction, Journal of Female Pelvic Medicine, Journal of Minimally Invasive Gynecologic Surgery and the American Journal of Obstetrics and Gynecology. I have published in the majority of the above mentioned journals and also in the following: Journal Sexual Medicine, The Female Patient, Journal of Pelvic Surgery, Urology, Mayo Clinic Proceedings, Current Opinions Obstetrics & Gynecology, and the Journal of Reproductive Medicine.

I have written nearly 100 peer-reviewed publications and 30 book chapters and one textbook with more than 25 papers and 9 book chapters specific to synthetic or allogenic grafts. (Please see Curriculum Vitae attached as Exhibit A.) I have authored or coauthored approximately 150 scientific abstracts and have performed surgery and given surgical lectures in more than 20 countries.

My first experience with mesh used to treat pelvic floor defects was in 1998, when I was trained on the Johnson & Johnson/Gynecare TVT sling for the treatment of stress urinary incontinence in Uppsala, Sweden. After returning to the United States, 5 other surgeons and I were among the first to implant the TVT retropubic synthetic sling. I became an advisor and preceptor on the procedure until approximately 2002. I estimate I taught more than 400 surgeons in my operating room on how to implant the TVT sling.

During the early 2000s until approximately 2009 I was using Gynemesh PS for laparoscopic sacrocolpopexies and as well as for some posterior vaginal wall augmentation during posterior repairs. In approximately 2003, I was approached by Gynecare/Johnson & Johnson and asked if I would go to France to evaluate the Transvaginal Mesh technique and, if I accepted, the company wanted me to sign an agreement guaranteeing my commitment to use the product. I explained that I would not sign a commitment to a surgical technique that I had not evaluated or even seen. Gynecare made a decision to sponsor my trip to France without my guaranteed commitment.

I went to France to meet Dr. Michele Cosson and Dr. Bernard Jacquetin and to evaluate TVM for pelvic organ prolapse in the operating room as well as in a laboratory setting. I expressed my opinions about both the pros and cons of this investigative new surgical technique to Gynecare and explained that I felt it was too dangerous to perform and to teach to other surgeons.

I was also asked by Ethicon Gynecare to travel to Belgium to meet with Dr. Jean De Leval to evaluate his new anti-incontinence technique known as the TVT-O but due to my schedule I declined the invitation. Several weeks later I attended a cadaveric training course on the same technique in Somerville, NJ. I discussed the pros and cons of this new technique with the Gynecare representatives during my visit. Several weeks later, Brian Luscomb of Gynecare came to observe my implantation of the TVT-O on a patient of mine. There were no complications but I made a decision not to use the product again.

In 2006 Gynecare, invited me to attend a cadaveric training session in Orlando, Florida on the single incision sling known as TVT-Secur. The course's primary instructor, Dr. Vincent Lucente, was also a key opinion leader for Gynecare. During the cadaveric training session I

discussed the shortcomings of the TVT-Secur device including: 1) razor blade insertion device and its extremely sharp nature 2) the poor releasing mechanism of the mesh sling from the insertion blade 3) the lack of conformity to dissection technique as discussed during a preceding lecture (I recommended putting one's finger into the incision to touch the ischiopubic rami to determine adequate insertion width and depth for mesh placement) and finally 4) the absolute necessity of performing a cystourethroscopy after the operation to assure patient safety.

Afterwards Dr. Lucente invited me to do a scientific study with him on the safety and efficacy of the TVT – Secur. I performed the TVT-Secur on 28 patients, and combined the intraoperative and postoperative data with Dr. Lucente's 77 patients. Our immediate post operative results revealed a dismal 71 % cure rate at 6 weeks. My overall cure rate at 6 weeks was 79% (22/28) and Dr. Lucente's cure rate using TVT-Secur was 68.8% (53/77). As a result, I felt I could no longer support the Gynecare TVT-Secur sling as an option for stress urinary incontinence and ceased use of the product.

In 2002-2003 I was contacted by US Surgical to be a medical advisor and one of the first surgeons in the country to perform a new innovative surgical procedure known as the Posterior IVS Tunneller. This procedure was utilized to treat posterior vaginal wall defects (rectoceles) and vaginal vault prolapse. After performing less than 10 cases and after reviewing the results from American and Australian surgeons, I abandoned its use due to high mesh extrusion rates, abscesses and persistent sinus tract formation.

From 2005-2008 Dr. Moore and I continued to use Gynemesh PS (Gynecare) and AMS polypropylene mesh for laparoscopic sacrocolpopexy and wrote the largest single center study on laparoscopic sacrocolpopexies mesh complications:

> Risk of mesh extrusion and other mesh-related complications after laparoscopic sacrocolpopexy with or without concurrent laparoscopic-assisted vaginal hysterectomy:

experience of 402 patients. Stepanian AA, Miklos JR, Moore RD, Mattox TF. J Minim Invasive Gynecol. 2008 Mar-Apr 15(2);186-96.

In this study 402 laparoscopic sacrocolpopexies were done over approximately 3.5 years. Our analysis, with a mean follow-up of 12 months, revealed the following complication: 1.1% dyspareunia, 0.2% infection rate, 0 erosion rate, and 1.2% vaginal extrusion rate. Dr. Moore and I have now performed more than 1600 laparoscopic sacrocolpopexies since 1998.

Dr. Moore and I currently perform approximately 450 surgeries annually for pelvic floor reconstruction. Over the last 4 years we have removed more than 500 pieces of mesh from patients suffering from complications. We presented 3 abstracts at the 2014 combined American Urogynecology Society and International Urogynecology Society Meeting:

1) Miklos JR, Chinthakanan O, Moore RD, et al. The IUGA/ICS Classification of synthetic mesh complications in female pelvic floor surgery: A multicenter study, AUGS/IUGA Scientific Meeting Washington, DC July 2014
2) Chinthakanan O, Miklos JR, Moore RD, et al. Mesh removal following sling/mesh placement: a multicenter study AUGS/IUGA Scientific Meeting Washington, DC July 2014
3) Chinthakanan O, Miklos JR, Moore RD, et al., Indications and surgical treatment of midurethral slings complications: a multicenter study, AUGS/IUGA Scientific Meeting Washington, DC July 2014

These three studies are the largest known studies on mesh complications and female reconstructive surgery. (At the AUGS/IUGA meeting, I was one of three faculty members to teach the postgraduate course on Pelvic Mesh Complications: Treatment and Surgery). The first of these three abstracts: *The IUGA/ICS Classification of synthetic mesh complications in female pelvic floor surgery: A multicenter study*, has been accepted for publication in the International Urogynecology Journal (2016). This is the largest published manuscript on the subject of mesh complications and female urogenital surgery.

Since the evolution of transvaginal slings and mesh procedures Dr. Moore and I have explanted more than 700 mesh devices, with more than 500 since 2010, including: Gynecare Prolift, Prolift +M, Prosima, TVT retropubic, TVT-O, and TVT – Secur slings. In our multicenter study on

mesh removal noted above, we removed midurethral synthetic slings in 83.3% (373/445) of those presenting with symptomatic mesh complications. A number of the midurethral slings removed were TVT-Secur slings.

I have reviewed numerous Instructions for Use (IFU) for a variety of medical products including mesh products in order to understand the proper way to use the device and to gain knowledge about the complications and adverse events associated with the devices.

I have extensive clinical experience with IFUs and instructing patients about the adverse events and risks contained in IFUs. I have gained expertise in IFUs through my extensive clinical experience reviewing IFUs and consenting patients regarding IFUs.

I have significant experience with pelvic repair surgery of all types with and without biologic or synthetic augmentation materials (i.e., grafts). I have multiple approaches to pelvic reconstructive vaginal surgery including transvaginal, abdominal, and laparoscopic and am considered well versed enough to lecture nationally and internationally.

I am familiar with the TVT-Secur specifically, as opposed to just mesh products and slings generally, as I have attended lectures, seen videos, read scientific articles and medical clinical trials, and reviewed the instructional and physician training materials for the TVT-Secur. I have personally been involved with a TVT-Secur study which proved to me that the device is an inferior product in terms of efficacy for stress urinary incontinence. I have personally removed a number of TVT-Securs with the most recent removal in the last 6 months. I know this because of our data collection needed to present the three scientific abstracts mentioned above.

II. EXPERT OPINIONS

All of my opinions in this report I hold to a reasonable degree of medical or scientific certainty.

Studies showed that the risks of TVT-S were greater than its benefits

Doctors who utilize products in their patients, and particularly products that will be permanently implanted in their patients' bodies, reasonably expect that the device's manufacturer will have taken into account all potential risks and weigh those risks against any benefits that the design of the product may provide. A reasonable medical device manufacturer will consider not only the risks associated with its device, but how those risks may be expected to affect the patient: how long they may last, how serious they may be, and whether and how the complication can be treated. If the problems that are known or reasonably may be expected to be associated with a particular design can cause problems that are serious, chronic or permanent, or that can be difficult or impossible to treat and resolve, no reasonable manufacturer would provide that device for permanent human implantation unless the benefits so far outweigh those risks that it could be justified.

Stress urinary incontinence ("SUI"), the condition that TVT-S was sold to treat, is not a life-threatening condition. While SUI may be uncomfortable and embarrassing, it is not painful or dangerous to the patient's health. Particularly when there were a number of other more or equally effective alternative surgeries and products available to treat this non-life threatening disorder, the risks inherent in the TVT-S design outweighed any claimed benefit.

Published medical literature and Ethicon's internal documents reflect the inadequate efficacy and safety of the TVT-S. For example, Ethicon's documents reflect "high 'failure' rates

across multiple centers" with TVT-S in 2007.[1] A study published in 2010 showed a 42% failure rate, and concluded that "Our experience shows that despite its good short-term efficacy, TVT-Secur is associated with a high recurrence rate of SUI. Therefore, TVT-Secur does not seem appropriate for SUI first-line management in women."[2] Gynecare's own internal document states " ... the TVT-Secur product is associated with inferior patient-reported and objective cure rates at 1 year, and higher reoperation rates when compared to standard mid-urethral sling (e.g. TVT/TVT-O) …" (ETH.MESH.05600922)

A January 22, 2007 internal e-mail reflects that 49 TVT-S complaints were reported to Ethicon from Germany in or before December 2006, including bleeding and hematomas, and further indicates that "most state 'failure incontinence after several weeks'."[3]

On October 22, 2007, the United Kingdom's National Institute for Health and Care Excellence (NICE) issued a recommendation regarding single-incision slings, like the TVT-S, stating that "'Current evidence on single -incision suburethral short tape insertion for stress urinary incontinence in women is limited in quality and quantity. Therefore this procedure should be carried out only in the context of controlled clinical trials with adequate duration of follow-up (for example, a minimum of 2 years).'"[4] An Ethicon employee summarized the NICE recommendation, stating "the reasons are limited clinical data (study design and quality, # of patients, limited length of follow-up) and the uncertainty expressed by the specialist advisers on the safety as well as the efficacy profile."[5] Another Ethicon employee responded, "I wonder why we have attracted such unusually harsh judgment (in draft). Is it another echo of our launching with less than gold-standard clinical data do you think?"[6] Ethicon launched TVT-Secur without any long-term clinical data (ETH.MESH.00134795) despite "worries" by KOLs' Nilsson and Artibani and Ethicon's European Marketing Manager, Harel Gadot.

(ETH.MESH.03172197) In fact, Ethicon board members had put in place an accelerated launch on the the product, and performing a clinical study would have caused a delay in the launch of the TVT-Secur. (Deposition of Patricia Hojnoski April 16, 2013 Page 100 Line 15 to Page 111 line 9)

On October 25, 2007, Dr. Aran Maree, Ethicon's Medical Director for Australia and New Zealand, attributed the failures to the product having been "launched as a substitute for TVT without enough clinical data to justify the roll-out," and that the TVT-S training program did not result in "competency in device insertion."[7] On November 2, 2007, Dr. Maree advised Catherine V. Beach, Worldwide Vice-President of Quality Assurance, that three seasoned surgeons experienced multiple 6-week failure rates-this included Prof. Malcolm Frazer, a surgeon who had performed about 700 TVT cases over the years, who experienced 13 failures out of 20 surgeries (a 65% failure rate).[8] The two other surgeons from Australia mentioned in Dr. Aran Maree's email, Dr Bruce Farnsworth and Prof. Marcus Carey, had approximately 30% and 40% failure rates respectively at 6 weeks post operatively. (ETH.MESH.00827141These surgeons reported that their failure rates with the TVT-S were significantly higher than those experienced with the TVT or TVT-O.

In late October 2007, Dr. Maree instituted a "quality block" on the TVT-S in Australia and New Zealand, which prohibited the product from being released.[9] Dr. Maree met on October 31, 2007 with Ethicon Medical Director David Robinson to "review with…Ethicon, the Australian and international postmarket surveillance results for [TVT-S]."[10] It was agreed in this meeting that the adverse outcomes reported in Australia were consistent with outcomes experienced elsewhere.[11] It was determined that "there was currently little significant surgical benefit in using SECUR over other existing procedures" and the decision was made to withdraw

the product from the Australian and New Zealand markets until further "high quality objective data" becomes available confirming optimal technique and enhancing product efficacy."[12] A Senior Product Manager in Australia explained that surgeons did not wish to be retrained on the TVT-S due to (1) lack of clinical evidence, (2) steep learning curve and surgeons are not prepared to risk their patients, and (3) IFU versus "nuances" are very different, and (4) current data suggests success rates of 65-70%, which was significantly lower than other available treatments.[13] By December 10, 2007, Australia had issued a "complete block" on the TVT-S.[14]

In an April 24, 2008 internal e-mail regarding comments attributed to Dr. Vincent Lucente, an Ethicon preceptor and "Key Opinion Leader," an Ethicon employee stated that "[w]hen [Dr. Lucente] went through his presentations with me he was quite scathing of…TVT Secur as having problems and being behind MINI ARC in terms of reliability. I do know that several comments were made in surge[r]y (off camera) about TVT Secur…."[15]

In a June 18, 2008 internal memorandum regarding communications with Key Opinion Leader physician Carl Nilsson relating to TVT-S, it was noted that the physician consultants advised that "[t]here is no documentation that Mini-Sling is safer and with equal efficacy as TVT."[16]Published clinical data also demonstrates the lack of efficacy of the TVT-S device. Ethicon's Medical Director, Piet Hinoul, and other surgeons, enrolled 194 subjects randomized to TVT-O versus TVT Secur.[17] One year follow-up outcomes were obtained for 85 TVT-O and for 75 TVT-Secur patients. Subjective reporting of SUI at one year was lower in the TVT-O group (8%) compared to TVT-Secur (24%) ($p<0.05$). The odds ratio (OR) for repeat incontinence surgery at one year was significantly greater for TVT-Secur (OR 2.3, 95% CI 1.9 to 2.7). Incontinence QOL was significantly better in the TVT-O group.

A Cochrane Review analyzed various single-incision devices used for urinary incontinence in women by interpreting the results of a number of reported studies and trials. Although Ethicon had already withdrawn the TVT-S from the market at the time of the Cochrane report, the report included the TVT Secur "so that level 1a data" would be "available in the literature to confirm its lack of efficacy."[18] Most of the review's findings were derived from studies involving TVT-Secur. The report noted that single-incision slings resulted in higher incontinence rates when compared with inside-out transobturator slings (30% vs 11 %; RR 2.55, 95% CI 1.93 to 3.36). The adverse event profile for single-incision slings was also noted to be substantially worse, and involved higher rates of vaginal mesh exposure, bladder/urethral erosion, and operative blood loss. Perhaps most significantly, overall results showed that the TVT-S was "considerably inferior to retropubic and inside-out trans obturator slings." The authors of the study concluded that "TVT-Secur is inferior to standard mid-urethral slings for the treatment of women with stress incontinence and has already been withdrawn from clinical use." Other studies have similarly concluded that the TVT-S has inferior efficacy when compared with other SUI devices.[19]

Ultimately, after the FDA issued a 522 order for the TVT-S in January 2012 requiring clinical studies to demonstrate the safety and efficacy of the device, Ethicon withdrew the TVT-S from the market.

As a physician who has regularly used various medical devices to treat stress urinary incontinence, and who has worked with medical device manufacturers in conducting clinical studies and in evaluating SUI treatment devices before and after marketing, it is my opinion that Ethicon failed to adequately test the TVT-S design before marketing the device for implantation into women. A properly-conducted clinical study conducted prior to marketing the TVT-S

would have demonstrated to Ethicon that the TVT-S was not as effective as available alternative treatments and devices, and created the potential for unreasonable risks.

Ethicon never had any data, clinically or otherwise, to support the use of the TVT-S device. To the contrary, all of the information available to Ethicon demonstrated that the efficacy of the device could not be established. In light of the lack of proof of efficacy, the significant risks or increased risks associated with the device outweighed any possible benefits and rendered the product unreasonably dangerous.

Design Flaws of TVT-Secur

Although my understanding is that Ethicon utilized the TVT and TVT-O as predicate devices in its 510(k) application to the FDA, these devices are completely different from the TVT-Secur.

In fact, a key opinion leader from Australia, Prof. Malcolm Frazer, said that TVT-Secur is so "utterly different to the other TVTs that it probably shouldn't be called a TVT"[20]. For example, the inserters used in the TVT-Secur had never been used before and the length of the tape were markedly different and made the TVT-S more prone to fail, as the angle of correction at the urethra was often not maintained[21]. The sharp edges of the TVT-S insertion device tear tissue upon implantation and removal, which can cause or contribute to complications, including pain, inflammation, and erosion.[22]

The TVT-S insertion method and design often caused the anchoring to dislodge, difficultly in properly tensioning the mesh, difficulty in removal of the insertion device after fixation, and lower success rates than other available SUI products.[23] In 2007, Ethicon's Quality Board conducted an analysis of the TVT-S in response to product-related complaints in Australia, which revealed that implant pull-outs with the inserter and difficulty in removing the

inserter were the two most significant complaints in the United States.[24] In fact, this was such an issue that key opinion leader and preceptor Dr. Vince Lucente recommended a technique not described in the TVT-Secur IFU: "Dr. Lucente has also found the placement of a very narrow malleable retractor (such as those used in ENT surgery) between the mesh and the inserter to be helpful in creating stability for the mesh while removing the inserter." (ETH.MESH.07396540)

In an August 19, 2007 internal PowerPoint presentation, an Ethicon marketing manager identified the following complications with the TVT-S: (1) insertion difficulties; (2) releasing difficulties; (3) fixation tips not staying in place; (4) bladder perforations; (5) excessive bleeding; (6) failures – tensioning.[25]

The design flaws listed above will cause pain, tissue damage, inflammation, and the mesh will shift and move, curl and scar in asymmetrically, and become too tight.

Particularly because there was no evidence to indicate or demonstrate that this device was as or more effective than alternative treatments, the significant potential for the severe and permanent risks or increased risks associated with the TVT-S design, as set forth above, outweighed any alleged benefits and made the device not reasonably safe.

Failure to warn/inadequate instructions

As an active explanting surgeon for this particular transvaginal mesh, I have reviewed and am familiar with the Instructions for Use (IFU), Physician Training materials, and sales and marketing materials prepared by Ethicon for the TVT-S. I have also reviewed the IFUs for many other medical products that I have implanted and explanted in patients during the last 17 years I have been practicing urogynecology and pelvic reconstructive surgery.

Along with other information that is provided by the device manufacturer in promoting products and training physicians to use those products, physicians must be able to reasonably rely upon the product IFU to make informed decisions about whether and how to use a medical device. Relying on the IFU, for surgical technique, increases consistency between surgeons' technique and thus efficacy and complication rates. Gynecare's Medical Director, David Robinson MD, touted the importance of specifically following the TVT-Secur IFU in an attempt to shorten the learning curve. (ETH.MESH.03922618). Failure to communicate a consistent "best" technique can result in non-reproducible efficacy results and varying rates of complications. This was an ongoing problem for Gynecare as the TVT-Secur technique was variable (i.e. U versus Hammock) as well as markedly different. Internal documents suggest the TVT-Secur should have been launched as two separate products due to the two different approaches recommended in the IFU as "this would have reduced the misuse, confusion and reduced the learning curve" (ETH.MESH.09951087). The contents of the IFU should also assist and help the doctors analyze all of the potential risks that are associated with a product to be able to properly consider whether a particular product is an appropriate surgical option for a given patient.

Physicians also rely on information provided by medical device manufacturers in other forms besides the IFU, such as patient brochures, physician training materials, and direct communications with sales and marketing personnel and other company employees. In order to make an informed decision as to whether to use a particular product in a given patient, a reasonable physician would expect a medical device seller to provide all pertinent information known to the company that could impact a reasonable physician's decision to use that product. However, the TVT-Secur technique was consistently changing and not shared uniformly among

the surgeons and Gynecare sales representatives. (ETH.MESH.07396540) (ETH.MESH.01784435) Not only were the educational materials not updated or consistent but some Ethicon employees felt that using a preceptor was the best form of training (ETH.MESH.03921637), as this increases quality assurance. Internal documents revealed a lack of conformity in training and not all surgeons were trained by a physician preceptor but instead by CD, "watched a link-up" or a sales representative. (ETH.MESH.03921638) This "less then perfect surgeon training" was specifically noted by Mark Yale, Gynecare's Director of World Wide Risk Management. (ETH.MESH.00330141). The failure in the consistency of training is obvious and the results were detrimental in terms of patient safety and efficacy. Failure to provide physicians with relevant information bearing on the potential safety and efficacy of a product that is known to the manufacturer prevents physicians from making informed decisions about whether to utilize the product. This failure also prevents physicians from properly counseling patients in considering whether to consent to permanent implantation of the medical device.

Ethicon's TVT-S physician training was inadequate and improper

While the TVT-Secur should never have been sold given the defective design of the device, in my opinion the TVT-S required greater specialized training than previous generations of TVT devices. The TVT-S involved a new and difficult insertion technique that was not similar to other Ethicon products or other competing SUI slings available on the market. Introduction of a novel product/surgery requires the manufacturer to ensure proper training and instruction for physicians who will be utilizing the new device.

Dr. Ramy Mahmoud, Ethicon's Worldwide Vice President for Evidence Based Medicine and former Chief Medical Officer at Ethicon, testified that he recalled discussing with Ethicon's

Medical Director David Robinson and other surgeons the importance of proper technique in implanting the TVT-S and "how important the training was in order to adopt the correct technique in order to achieve the desired success rate."[26] Dr Maree testified that the TVT-Secur was a product that had either a substantially new technique or was significantly modified from the predecessor products (TVT and TVT-O) (Deposition of Aran Maree 7.22.13 page 137 line 8-16). Dr Maree also testified that Dr Frazer, an Australian KOL, also thought the device was a substantially new technique and a different product. (Deposition of Aran Maree 7.22.13 page 137 line 18-20 and page 139 line 2-7). It is my opinion that due to its novel technology, unproven efficacy and non reproducible technique, Ethicon should have, but failed to provide adequate and follow-up training.

Ethicon's documents reflect that early clinical experience demonstrated that the learning curve for TVT-S was longer than anticipated, particularly due to the unique mesh tensioning technique.[27] In an internal memo, Ethicon engineer and TVT-S co-inventor Daniel Smith identified the "implications" of achieving competency on the TVT-S: "extensive training requirements, possible loss of market share."[28] As Mr. Smith noted: "Do not underestimate the learning curve for a device which seems simple."[29] Dr. Vincent Lucente, an Ethicon consultant and preceptor, reported a 40% failure rate in his first 25 patients, and 30% of his first 77 patients.[30] Ethicon's Dr. Maree noted in an October 30, 2007 e-mail that given Dr. Lucente's reported failure rates it was "not at all surprising that we may have similar or higher failure rates here."[31] Another of Ethicon's physician advisors and Key Opinion Leaders, Carl Nilsson, advised the company in June of 2008 that his learning curve for the TVT-Secur was "100 patients before he was very good with very dry results."[32] Dr. TC Khoo, Ethicon's Vice President of Strategic Medical Affairs for Asia Pacific, suspected that TVT-S failures were

"related to operator based technique deployment."[33] Dr. Khoo recognized the important of addressing physician training issues and the need "to eliminate any possibility of product related issues while considering the adequacy of training and what is needed to properly rollout a device" so that patients do not get "the short end of the stick," and stated that the "responsibility of controlling the adequacy of training is critical."[34]

Ethicon's European Medical Director, Axel Arnaud, observed that Ethicon could not "ignore that some surgeons who have been able in the past to successfully perform TVT and TVT-O are now struggling to achieve the same results with Secur," and stated that he wished "the solution would just be to tell them to go back to their homework, but I am not sure it is the best one."[35] Ethicon's Medical Director Dr. David Robinson responded that "[i]t is just as clear that we are having some type of training problems and in order to prevent wide spread negative talk, I think we must take palliative steps quickly."[36] Despite this internal communication and information known or available to the company, no action was taken to revise the TVT-S training.

In an October 25, 2007 correspondence, Dr. Maree expressed his concern that the "current [TVT-S] training program may not result in competency in device insertion or result in clinical efficacy. There appear to be 'tricks' to insertion of the product and removal of the inserters which prevent dislodging the device in the process."[37] Dr. Maree stated that "the average practitioner finds it too complicated to insert correctly and cannot master the process," and due to surgeon's inability to achieve competency in inserting the product, recommended "restrict[ing] access to those who can."[38]

Despite the information known or available regarding the importance of thorough training and the difficulty in the TVT-S procedure, Ethicon did not limit the sale or marketing of

the TVT-S to only experienced and trained physicians. To the contrary, Ethicon often relied on engineers and sales personnel to "train" physicians on the implantation of the TVT-S device.[39] In fact, to address TVT-S training concerns, Ethicon's Quality Board in 2007 recommended that the company "keep [the TVT-S] product in market to train people."[40]

Additionally, in making an informed decision of whether or not to use a permanent medical implant, the physician must be warned not only of the true difficulty of the procedure, but also the potential adverse events that may be associated with the product, including the frequency, severity, duration and potential permanence of those adverse events. If a manufacturer knows that a complication can be chronic, severe or permanent, it should provide that information to the people who will be using its products or having those products implanted in their bodies. This concept is reflected in internal Ethicon communications from Meng Chen, Ethicon's Associate Medical Director for Worldwide Quality, wherein she urged the company to change the IFU for TVT-S because "[o]ur post-market knowledge with these products are much more than what we have in the IFUS of all three types of TVTs,"[41] and also expressed concern that any reference in the TVT-S IFU to certain identified complications as "transitory" (or temporary) is inadequate, and stating that "from what I see each day, these patient experiences are not 'transitory' at all."[42] As Ms. Chen explained to Ethicon's upper management, "One of the paths for a better pre-operative consent is to provide an updated IFU to the operating physicians that reflect[s] the current knowledge of the manufacturer's on the potential adverse reactions."[43]

It is my opinion that certain statements in the TVT-S IFU are false and misleading because they contradict information known or at least available to Ethicon, according to Ethicon's own documents.

The IFU states that "[a]nimal studies show that implantation of PROLENE mesh elicits a minimal inflammatory reaction in tissues, which is transient…." Contrary to this statement, however, Ethicon's documents reflect that the polypropylene material used in the TVT-S device causes an "excessive" and "chronic" foreign body reaction and "intense" and "chronic" inflammation.[44]

The information provided to physicians and patients for the TVT-S device, including the IFU and promotional materials, did not properly warn about the risks associated with the TVT-S. Even for risks that were disclosed, the IFU and other materials provided by Ethicon did not adequately convey the frequency, severity and duration of the risks that were disclosed.

There were numerous serious safety risks associated with the TVT-S that were not included in the TVT-S IFU, including but not limited to: chronic or permanent pain; voiding dysfunction; dysuria; abscess formation; painful intercourse that may not resolve; neuromuscular damage; leg pain; recurrence (of incontinence); significant bleeding (including hemorrhage or hematoma); one or more revision surgeries may be necessary to treat adverse reactions; the mesh is a permanent implant and significant dissection may be required if the mesh needs to be removed; urge incontinence; urinary frequency; urinary retention; adhesion formation; atypical vaginal discharge; or that exposed mesh may cause discomfort to a sexual partner during intercourse.[45]

There was never any warning provided that the polypropylene material used in the TVT-S mesh causes intense, chronic and excessive inflammation and foreign body reaction. Ethicon failed to warn that the inflammatory response to the TVT-S mesh material was directly correlated to shrinkage and pain.[46]

Ethicon's internal documents reflect that the contraction/shrinkage rate associated with its pelvic repair mesh products was as high as 20% to 40% (or higher), and that this contracture was associated with deformation of the mesh which can cause pain.[47] However, no warning was ever provided about the frequency, permanency or severity of this increased risk.

Ethicon never provided any warning of the risks of nerve damage, nerve entrapment, nerve tethering or nerve severing caused by the TVT-S mesh after implantation.[48]

Ethicon did not adequately warn that the sharp insertion device created the risk of nerve damage and tissue injury upon implantation.

Ethicon failed to warn about the potential for vaginal deformation caused by the mesh.

Ethicon failed to warn that the safety and efficacy TVT-S had never been evaluated in clinical trials prior to being marketed.

Ethicon failed to provide any warning that the clinical data available to the company showed lower efficacy rates and higher complication rates when compared with alternative available devices and treatments for stress urinary incontinence.

Ethicon provided no warning of injury due to the device remaining attached to the inserter after implantation.

Ethicon failed to warn about the difficulty of removing the TVT-S mesh in its entirety once it is implanted.

Ethicon failed to provide any instruction or direction as to how to address complications, or what to do in the event mesh removal was necessary. In fact, before the TVT-S was sold, Ethicon's internal documents reflect concern that providing instruction or direction regarding removal of their mesh would cause physicians to worry that mesh removal could be necessary, and indicate concern that "overinformation" about mesh removal would be "digging my own

grave."[49] Doctors expect a reasonable medical device manufacturer to warn them about all potential risks known to be associated with its product, regardless of how that may affect their attitudes towards the product.

Ethicon did not provide any warning to physicians or patients that the surgical procedures necessary to remove mesh can themselves cause serious, long-term complications.

Having read and relied upon IFUs for urogynecologic medical implants over the past 17 years, it is my opinion that the type of information detailed above should be communicated to surgeons so that they can make safe treatment choices for their patients. Even if Ethicon did not have knowledge of the information at the time of the products' launch, once this information became available, the company should have made changes to the IFU and otherwise made reasonable efforts to ensure that physicians continue to have the information necessary to make informed and safe treatment decisions for patients. If physicians are not fully and timely informed of all of the information known to the manufacturer bearing on the safety and efficacy of the product, they cannot be expected to perform an adequate risk-benefit analysis or obtain adequate informed consent from their patients.

Doctors not only must rely on the manufacturer to provide adequate warnings about the products risks, but also to provide adequate instruction on how to safely use the product so as to avoid unnecessary risks. The documents that I have reviewed indicate serious inadequacies in the instructions for implantation of the TVT-S, which created even greater potential for complications. In December 2006, Ethicon's European Medical Director, Axel Arnaud, reported to Daniel Smith (Ethicon engineer and co-inventor of the TVT-S) and Dr. David Robinson (Ethicon's Medical Director) that surgeons, even Key Opinion Leaders "who have been correctly trained and who have passed the learning phase, are raising concerns about the efficacy of the

TVT Secur…. They are asking for clear recommendations about the way to perform the procedure, in particular about the size of the dissection, the tension to be given to the tape and the way to perform a cough test."[50] No such instructions were in the initial TVT-S IFU, and no such instructions were ever provided for the TVT-S.

An Ethicon marketing manager identified several technique-related complications with the TVT-S in an August 19, 2007 internal PowerPoint presentation, including: (1) insertion difficulties; (2) releasing difficulties; (3) fixation tips not staying in place;… (5) excessive bleeding; (6) failures – tensioning.[51] The IFU vaguely and generally references bleeding, and "overcorrection" and "undercorrection," but fails to offer any other information about these risks, the extent or severity of these risks, or how to minimize or avoid these risks.

Ethicon's Australian and New Zealand Medical Director Dr. Aran Maree similarly reported that Ethicon Key Opinion Leaders had advised that "the [TVT-S] IFU is fundamentally misleading" because "tension-free, tension-less and placement with no tension are complete misnomers."[52] On November 2, 2007, Dr. Maree noted that "It is my understanding that some suggestions had come out in the form of (i) increased tension required with this mesh with 'pillowing of peri-urethral tissues required', (which is quite the opposite of TVT-O recommendations), as well as (ii) new tips for minimal dissection when introducing the product. We also discussed the fact that at this time some or all of these suggested changes may not be incorporated into the [IFU] or technical training material."[53] Despite this information known or available to Ethicon, no such information was included in or added to the TVT-S IFU at any time.

A medical device manufacturer which knows or believes that its devices cannot be safely used in any segment of its patient population must make reasonable efforts to warn and instruct

its consumers regarding a restriction for those patients. According to the TVT-S IFU, the only restricted patient populations for the TVT-S were patients on anti-coagulation therapy and patients with urinary tract infections. This implied to physicians that the use of the TVT-S device in all other patients was acceptable. If Ethicon knew or believed that there may be risks specifically associated with the use of its TVT-S product in any given category of patients, it was obligated to so advise the physician users of the products.

General causation opinions

I am familiar with the published literature and the internal Ethicon documents describing complications associated with the TVT-Secur device, as discussed above. I have also personally observed, treated and explanted mesh from patients implanted with TVT-Secur.

Based upon my education, training, experience and knowledge, and my familiarity with the published literature relating to this subject, as well as my review of internal Ethicon documents describing complications, it is my professional opinion to a reasonable degree of medical certainty that the injuries and complications that patients experience with the TVT-Secur and that I have personally observed, diagnosed and treated involving the TVT-Secur products are directly attributable to the defective design of these products as described previously. These complications include, but are not limited to, the following:

1. Chronic pelvic pain;
2. Chronic inflammation of tissue surrounding mesh;
3. Excessive scar plate formation and contracture of mesh, causing pain;
4. Erosion of mesh into the bladder and urethra and exposure of mesh in the vagina;
5. Pelvic floor muscle spasm;

6. Direct trauma to organs and tissues and nerve injury and damage caused by the TVT-Secur insertion device;

7. Nerve damage or nerve entrapment as a result of mesh scarification and fibrotic bridging;

8. Dyspareunia;

9. Recurrence of stress urinary incontinence and urge incontinence;

10. Urinary retention;

11. Encapsulation of mesh (mesh covered in thick scar);

12. Vaginal deformation;

13. Infection as a result of the mesh, including bladder infections, vaginal infections, chronic urinary tract infections, and abscesses; and

14. Fistulae.

III. DATA CONSIDERED IN FORMING MY OPINIONS

I considered the documents identified in the footnotes of this report, as well as those listed in Exhibit B attached hereto.

IV. EXHIBITS WHICH I PLAN TO USE AS A SUMMARY OF OR IN SUPPORT OF MY OPINIONS

I may use documents that I reviewed and which are identified above, female pelvic floor models and illustrations, samples of the TVT-Secur, and summaries of literature that I may prepare.

V. COMPENSATION FOR MY REVIEW, STUDY AND TESTIMONY

I charge $1,000 per hour for review and study of records. I charge a 50% premium on records that must be reviewed within 30 days. Deposition fees are $4,000 per half day and $8,000 per full day. Court appearances are $12,000 per day.

VI. OTHER CASES IN WHICH I HAVE TESTIFIED AS AN EXPERT AT TRIAL OR BY DEPOSITION IN THE LAST FOUR YEARS

P. Ashurst, Plaintiff Deposition, AZ; Attorneys: Rowley Chapman Barney & Buntrock

Bonnie Clarida, Plaintiff Deposition, GA; Attorneys: Ellerin & Associates

Donna Cisson v. C.R. Bard, Plaintiff Deposition, GA; Attorneys: Blasingame, Burch, Garrard & Ashley

DiLeonardo v. Boston Scientific, Plaintiff Deposition, GA; Attorneys: Shook, Hardy & Bacon, LLP

Crogan v Weinreb, Plaintiff Deposition, GA; Attorneys: Baxter, Baker, Sidle, Conn & Jones

Holizna v. Boston Scientific, Plaintiff Deposition, GA; Attorneys: Blasingame, Burch, Garrard & Ashley

Russell v. Miklos, et al, Defendant Deposition and trial testimony, GA; Attorneys: Carlock, Copeland & Stair, LLP

Tonya Graves v. Bard, Plaintiff Deposition, GA; Attorneys: Blasingame, Burch, Garrard & Ashley

Rule 26 C.R.Bard MDL, Plaintiff Deposition, GA: Attorney: Blassingame, Burch, Garrard & Ashley

Atwell-Jackson v. Bard, Plaintiff Deposition, GA; Attorneys: Blasingame, Burch, Garrard & Ashley

Kathy Trammel v. Bard, Plaintiff Deposition, GA; Attorneys: Blasingame, Burch, Garrard & Ashley

Sandra Garcia v. Ethicon, GA; Attorneys: Clark, Love & Hutson

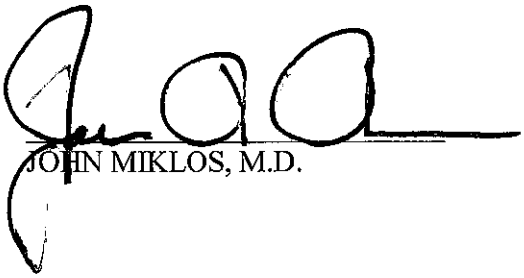
Hazel Lewis v. Bard, FL; Attorneys: Potts Law firm

Pamela Drebronkart v. Bard, GA; Attorneys: Levin Law firm

Beryl Cole v. Mentor Corp, GA; Attorneys: Potts Law firm

Elizabeth Way v. Bard, GA; Attorneys: Alystock, Witkin, Kreis & Overholtz

Melissa Watson v. Mentor, GA; Attorneys: Alystock, Witkin, Kreis & Overholtz



JOHN MIKLOS, M.D.

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[1] ETH.MESH.00642330.

[2] Cornu JN, et al. (2010) "Midterm prospective evaluation of TVT-Secur reveals high failure rate." Eur Urol. 2010 Jul; 58(1): 157-61.

[3] ETH.MESH.0324086.

[4] ETH.MESH.03922228 (10/25/07 internal e-mail).

[5] Id.

[6] Id.

[7] ETH.MESH.00642330.

[8] ETH.MESH.00312179.

[9] A. Maree 7/22/13 depo., 189:14-190:22.

[10] ETH.MESH.00823421.

[11] Id.; See also, ETH.MESH.00874445; ETH.MESH.04126728.

[12] ETH.MESH.04126728.

[13] ETH.MESH.04127331.

[14] ETH.MESH.04127062.

[15] ETH.MESH.05009194.

[16] ETH.MESH.04048515.

[17] Hinoul P., et al., A randomized controlled trial comparing an innovative single incision sling with an established transobturator sling to treat female stress urinary incontinence. J Urol, 2011. 185(4): p. 1356-1362.

[18] Nambiar A, et al., Single-incision sling operations for urinary incontinence in women. Cochrane Database of Systematic Reviews 2014, Issue 6. Art. No.: CD008709.

[19] Hota, Lekha S., MD, et al., TVT-Secur (Hammock) Versus TVT-Obturator: A Randomized Trial of Suburethral Sling Operative Procedures. Female Pelvic Med Reconstr Surg. 2012, Jan-Feb; 18(1): 41-45 (47% cure rate for the TVT-Secur versus 91% cure rate for the TVT-O); Maslow K, et al. Randomized clinical trial comparing TVT Secur system and trans vaginal obturator tape for the surgical management of stress urinary incontinence. Int Urogynecol J (2014) 25:909-914 (63% cure rate for the TVT-Secur versus 86% cure rate for TVT-O). Hamer MA, Larsson PG, Teleman P, Bergquist CE, Persson J. One year results of a prospective randomized, evaluator-blinded, multicenter study comparing TVT and TVT Secur. Int Urogyn J (2013) 24:223-9. Wang Y, Li F, Wang Q, Yang S, Cai X, Chen Y (2011) Comparison of three mid-urethral tension-free tapes (TVT, TVT-O, and TVT Secur) in the treatment of female stress urinary incontinence: 1-year follow-up. Int Urogynecol J 22:1369–1374

[20] ETH.MESH.00327062

[21] Deposition of Dr. David Robinson, 7/24/13, page 116, lines 5-22.

[22] ETH.MESH.04474756 (In a study conducted by Ethicon-consulting Key Opinion Leader physicians, the authors concluded that "there was also an increased incidence of mesh exposure in the TVT-S group. Although the etiology of this complication is unclear, we theorize that the sharper edges of the TVT-S introducer potentially create more trauma to the vaginal epithelium and may result in higher erosion rates.").

[23] ETH.MESH.0329316 (11/6/06 internal e-mail to Ethicon Medical Director revealing issue regarding removal of TVT-S device upon removal of insertion device, and concerns of high rates of injuries when the mesh does not separate from insertion device during removal, causing the mesh to be moved or pulled out with the inserter); ETH.MESH.00572598 (5/17/07 presentation by Ethicon European Medical Director) ("Key Issues in Europe" include "[s]ome key experts and non-experts are disappointed [in TVT-S]," and "[k]ey experts are abandoning the procedure.").

[24] ETH.MESH.06051286.

[25] ETH.MESH.02105223.

[26] Rahmy Mahmoud, M.D. 7/16/13 depo., 380:5-10.

[27] ETH.MESH.03922618 (3/14/07 internal e-mail from Ethicon Medical Director to Ethicon European Medical Director stating that first human study revealed "that the learning curve is longer than we thought, mesh tensioning is different than kits with sheaths and that following the IFU is important."); ETH.MESH.02105223 (8/19/07 Worldwide Marketing Team Update PowerPoint on TVT-S) (noting TVT-S learning curve was longer than anticipated, that there was a "lack of right training," and a "lack of clinical data.").

[28] ETH.MESH.00858636.

[29] Id.

[30] ETH.MESH.02105223.

[31] ETH.MESH.03845446, p. 1.

[32] ETH.MESH.04048515 (6/18/08 internal report), p. 3.

[33] ETH.MESH.00642325, p. 3.

[34] Id.

[35] ETH.MESH.01784428, pp. 2-3.

[36] Id., p. 1.

[37] ETH.MESH.00642330.

[38] ETH.MESH.00642327.

[39] ETH.MESH.0329557 (3/1/07 internal e-mail indicating more than 50 reports of TVT-S failures with some requiring intervention, to which Ethicon responded by sending engineer Dan Smith to "retrain preceptors and others."); ETH.MESH.02105223 (8/19/07 internal PowerPoint) (noting "lack of local budgets [for TVT-S training] leading to local decision for self trained surgeons (CD, sales force)"). See also, ETH.MESH.00330141.

[40] ETH.MESH.00874445, p. 17.

[41] ETH.MESH.04092868 (12/19/08 internal e-mail).

[42] ETH.MESH.04094863 (1/29/09 internal e-mail).

[43] ETH.MESH.04092868.

[44] ETH.MESH.05455879 (1/18/03 notes from Surgeon Panel Meeting) - "Polypropylene - initial acute inflammation then chronic foreign body reaction."); ETH.MESH.02017153 (3/06/07 Minutes from an Ethicon Expert Meeting) ("Polypropylene meshes might not be improvable in terms of shrinkage, we may need a completely new material…."); ETH.MESH.00271215 (10/29/08 internal e-mail) – Polypropylene is "the best of a bad lot re integration/retraction" and "there is a need to develop grafts that mimic the human tissue mechanical properties."); ETH.MESH.00680021 (11/12/08 internal e-mail) – "Polypropylene creates an intense inflammatory response that results in rapid and dense incorporation into the surrounding tissue. The excessive inflammatory reaction caused by heavyweight meshes tends to form a scar plate around the prosthetic that results in a firm and contracted mesh."); ETH.MESH.03722384 (9/17/09 internal e-mail) – "We're seeing a lot of work published that indicates that polypropylene produces an ongoing, chronic inflammatory reaction…Might be better off working with something that is less reactive, like PVDF."); ETH.MESH.01238483 (4/27/09 internal memo) – "Vaginal discomfort is the most troublesome complication of transvaginal mesh and mostly determined by ... Host interaction with the mesh as it relates to chronic inflammation, excessive fibrosis and 'stiffness' from scar plating creating nerve entrapment and or nerve tethering."'); ETH.MESH.05237872 (Nov. 3-4, 2010 "Mesh and Textile Summit") – PowerPoint addressing downsides of "old fashioned" (i.e., polypropylene mesh): "Excessive foreign body reaction; Chronic inflammation; Decreased fibro collagenous ingrowth; Scar plate formation; Shrinkage from bridging fibrosis.").

[45] ETH.MESH.01037447, p. 6 (TVT-S Clinical Expert Report prepared by Ethicon Medical Director indicating abnormal bleeding, hematuria, leg pain, hematoma, venous thrombosis, abscess formation, and death as potential TVT-S complications).

[46] ETH.MESH.03906525 (1/27/06 internal PowerPoint by Ethicon's European Medical Director), Slide 30 ("Mesh must not shrink. Rationale: to preserve the vaginal anatomy and to avoid recurrences. Theory: The scar tissue naturally shrinks up to 70% in the wound area during the healing process. Physiological wound contraction increases with the extent of inflammation. Shrinkage could be minimized by reducing the inflammatory reaction: well tolerated material, large pores."). ETH.MESH.01752532 (9/18/06 internal e-mail) - "As soon as meshes are considered as a prosthesis in the pelvic floor region, the biomechanical consequences of implantable meshes are not without concern. The body generates an inflammatory response to the prosthetic that results in more ore less sever scar plate formation, increased tissue stiffness and possible shrinkage of the mesh."); ETH.MESH.02247342 (1/21/09 internal PowerPoint) "Importance of Pore Size. Polypropylene creates an intense inflammatory response that results in rapid and dense incorporation into the surrounding tissue. The excessive inflammatory reaction to heavyweight Polypropylene tends to form a scar plate around the prosthetic that results in a firm and contracted mesh…Bridging occurs in all mesh modifications with a granuloma size around each mesh fiber exceeding more than half to the pore size of the mesh. Desirable pore size >1mm. [citing literature from 2005 and 2006].").

[47] ETH.MESH.03910418 (11/25/02 internal e-mail regarding, inter alia, mesh shrinkage in TVT) – "As we discussed the shrinkage rate is influenced by many parameters as the degree of fibrotic reaction is dependent on the mesh material/weave/width etc. I remember that Axel [Arnaud, Ethicon's European Medical Director] was using 30% shrinkage as a rule of thumb…."); (ETH.MESH.00584846 (5/10/04 internal e-mail) – "Their [consulting physicians'] main concern is now the shrinkage of the mesh which may lead to pain, dyspareunia…Indeed now that they have tremendously improved the technique and lowered the erosion rate what needs to be improved is the shrinkage of the mesh (in this case Gynemesh soft)."); ETH.MESH.00681364 (9/07/04 internal report) – "GYNEMESH PS today has a 'swirling effect' causing what doctors have expressed as 'shrinkage or contraction of the mesh'. It isn't the mesh that's contracting, it's the tissue that seems to be 'bunching' up resulting in the desire to have a more 'tension-free' fixation."); ETH.MESH.05574759 (1/18/05 internal e-mail reporting surgeon's experience with use of Gynemesh in pelvic floor repair) – "a. contraction pulls against the side wall and causes pain b. it causes a hard tissue which can be felt by patient and sexual partner c. it can lead to a balling up of the mesh which is very uncomfortable d. it can lead to suture line dehiscence e. it can lead to prolapse recurrence…. 5) he confirmed our thoughts regarding the correlation between inflammation, foreign body response and scar formation."); ETH.MESH.05246528 (3/10/05 report discussing areas impacting clinical outcomes with mesh) – "Tissue contraction (20-40%), Scar formation = recurrence or dyspareunia…Erosions - potentially address through technique."); ETH.MESH.04020138 (4/13/05 e-mail from Ethicon engineer) – "In pelvic floor repair even with the PSM, we have seen some scar contracture which translates into procedural complications… [S]urgeons who are our consultants on the Prolift product are asking for a mesh which is better than PSM in this area." (Id.). "The surgeons attribute these conditions [recurrence of prolapse, pain, stiffness, erosion and discomfort during sex] to scar contracture."); ETH.MESH.03906579 (6/09/05 interview with Ethicon European Medical Director, Axel Arnaud) – "Shrinkage is due to an excessive scarring process...in a few cases it led to vaginal distortion impacting the sexual life. Thus, the procedure must be used cautiously in sexually active women."); ETH.MESH.05243265 (1/24/06 e-mail discussing meeting with consulting physicians in Europe) – "Their [physicians'] main concern is the believe that the Prolene Soft material over time contracts. Thus creating the potential for failures and/our erosions."); ETH.MESH.03906525 (1/27/06 internal PowerPoint by Ethicon's European Medical Director), Slide 30 ("Mesh must not shrink. Rationale: to preserve the vaginal anatomy and to avoid recurrences. Theory: The scar tissue naturally shrinks up to 70% in the wound area during the healing process. Physiological wound contraction increases with the extent of inflammation. Shrinkage could be minimized by reducing the inflammatory reaction: well tolerated material, large pores."); ETH.MESH.00870466 (6/2/06 Expert Meeting Memo) ("Shrinkage of 20% means reduction of mesh area to 64%."); ETH.MESH.10511708 (12/12/06 internal R&D PowerPoint "State of Knowledge in Mesh Shrinkage") – "'Shrinking meshes' are a topic of discussion and concern among hernia surgeons. It is believed that mesh shrinkage may lead to patients' discomfort, chronic pain or hernia recurrence…. Mesh shrinkage was evaluated at different time points and the reduction of the calculated area was 12% at one month, 24% at 3 months, 29% at 6 months and 34% at 12 month. [citing 2006 literature]"); ETH.MESH.02017153 (3/06/07 Minutes from an Ethicon Expert Meeting) ("Polypropylene meshes might not be improvable in terms of shrinkage, we may need a completely new material… Unmet clinical needs: No shrinkage/no long term contraction… Severe contraction →

Dyspareunia → sexual function ↓."); ETH.MESH.00821702 (9/26/07 internal memo reporting results of 2004 European clinical study of Prolift), Slide 23 – ("Functional results: painful mesh shrinkage. Painful mesh shrinkage (at vaginal examination) – 21 patients (19.6%)…. Correlation between painful mesh shrinkage and dyspareunia but not systematic."); ETH.MESH.01818382 (12/20/07 Ethicon Mesh Contraction preclinical study) (27% shrinkage (measured radiographically) and 23% (measured by image analysis), as well as fibrotic bridging, folding, rippling and distortion, for Prolene Soft in the subcutaneous model after 13 weeks implantation); ETH.MESH.00836975 (3/28/08 internal e-mail from Ethicon Worldwide Medical Director responding to question about how to identify and complications associated with mesh shrinkage) – "First, the mesh doesn't shrink. As collagen grows into the mesh, the entire mass contracts…. In the patient, it can be noted with stiffening of the vaginal wall (causing dyspareunia) or bunching of the Prolift straps (which can cause pain). All patients getting mesh get contraction."); ETH.MESH.01238483 (4/27/09 internal memo) – "Vaginal discomfort is the most troublesome complication of transvaginal mesh and mostly determined by ... Host interaction with the mesh as it relates to chronic inflammation, excessive fibrosis and 'stiffness' from scar plating creating nerve entrapment and or nerve tethering."); ETH.MESH.02227282 (11/14/09 PowerPoint), p. 7 – "Folding of mesh is one cause for erosion and pain."); ETH.MESH.05479695 (Nov. 3-4, 2010 Mesh and Textile Summit PowerPoint) – "There is no place for a 'Heavyweight Mesh' in modern pelvic floor repair… Polypropylene Mesh – Small pore size (<1 mm)… Issues with small pore meshes –…Increased inflammatory response results in rigid scar plate formation – Scar plate responsible for shrinkage of mesh up to 40% [citing published literature from 2002 and 2004].").

[48] ETH.MESH.00870466 (6/20/06 notes re: Ethicon Expert Meeting) – "Meshes can cause Nerve damage due to mechanical irritation (mesh bears on nerve) …. Vaginal pain after implantation of meshes is rare, but feared, since there is not real treatment option"); HMESH_ETH_01800994 (10/11/06 internal e-mail chain discussing mesh pain/shrinkage literature) ("The take home message from the article was that chronic pain can be associated with placement of a mesh device…. [The author] continues to point out that neuropathy-related complaints after intraoperative damage of nerve fibers is associated with pain immediately after surgery, however, the onset of chronic pain as a consequence of the 'foreign body reaction' is typically more than one year after the hernia repair. He goes on to point out that patients that reported chronic pain demonstrated nerve fibers and fascicles in the interface of the mesh upon examination upon removal."); ETH.MESH.01238483 (4/27/09 internal memo) – "Vaginal discomfort is the most troublesome complication of transvaginal mesh and mostly determined by ... Host interaction with the mesh as it relates to chronic inflammation, excessive fibrosis and 'stiffness' from scar plating creating nerve entrapment and or nerve tethering.").

[49] ETH.MESH.08167452 (10/3/00 internal e-mail in response to e-mail from physician consultant regarding instructions for TVT removal procedure) – "Theoretically, I can envisage no need for TVT explant. And I agree…that if we, in any way, publish such an information, we start giving the reason to believe that explant of the TVT may be needed in some circumstances. Frankly, I do not want to dig my own grave...!"…"In my opinion, we must be very careful in avoiding 'overinformation'").

[50] ETH.MESH.00519479.

[51] ETH.MESH.02105223.

[52] ETH.MESH.06051155.

[53] ETH.MESH.00312180.